K080445

JUL 16 2008

510(k) Summary

This 510(k) is submitted by:

Class One Orthodontics, Lubbock, TX
Contact person: Judy Ribordy,
Date of submission:

Device Name: Lion Se One Step Orthodontic Adhesive

Classification name: Adhesive, bracket and tooth conditioner, resin

Identification of a legally marketed device to which we are claiming equivalency

We have chosen our predicate device to be:

Reli- On One Step Adhesive bonding system,
ClassOne Orthodontics, 5064 50th St. Lubbock, TX

Device description

Lion Se is a one step orthodontic adhesive. It comprises of two major components, i.e., a viscous polymeric resin paste and a watery component called, Activator. The formulation of Lion Se adhesive is identical to the predicate adhesive, except that the Lion Se paste contains 2% of a Selenium compound . This is a modified acrylic monomer which polymerizes & becomes an integral part of the final cured adhesive. The paste is delivered from a syringe, while the activator is dispensed from a squeeze bottle. Besides the paste & the activator, the product kit contains a preloaded syringe of etchant (35% phosphoric acid solution), brushes to apply the activator on the tooth and a stack of mixing pads for easy transfer of the activator.

The tooth to be bonded is etched with the etchant (conditioner) for 10-20 seconds, followed by a water rinse. The activator is applied to the surface of the etched tooth and also to the base of the bracket. The paste is then applied to the base and the bracket is placed on the tooth in the desirable clinical position. In about a minute the bracket is securely fastened to the tooth. Optimum strength is achieved in 24 hours. The product comes with a detailed instruction for use pamphlet.

Performance criteria

The important criteria for the optimum performance of this product are:

(1) Set time

(2) Shear bond strength

Set Time:

This is the time available to the clinician while manipulating the bracket to optimize the bracket location on the tooth. If the set time is too short, the clinician will not be able to place the bracket in the proper position before the adhesive sets up. Conversely, if the set time is too long, the bracket can "drift" from the desirable position, requiring constant attention until the final set has taken place. Typically the set time for one-step adhesives is in the range of 20-25 seconds. The experimental procedure for determining the set-time is outlined here.

Experimental procedure for determining set-up time for One-step (or No-Mix) adhesives.

Methods & Materials

Materials used for performing set-up time Testing

(a) Freedom MIM Roth brackets (upper centrals)
(b) Acrylic rod (1" radius)
(c) sand paper (100 grit)
(d) explorer or an equivalent pointed probe
(e) Lion Se test adhesive and Reli-On predicate adhesive.
(f) stop-watch or equivalent

Experimental method

Using the sand paper, abrade the acrylic rod surface. Apply Lion Se activator on the base of the bracket and on the sanded surface of the acrylic rod. Apply a thin layer of the adhesive paste on the bracket base. Immediately place the bracket on the acrylic rod (pretreated with activator) and start the stop watch. Using an explorer move the bracket slowly back and forth until the adhesive sets up and its gets difficult to manipulate the bracket. Note the time elapsed. This is the set-time in seconds. Repeat with 5 different samples and report the average value. Repeat entire procedure for Reli-On (predicate) device.

Shear bond strength:

The primary mode of stress transfer to the bracket in the oral environment is through shear. The brackets are dislodged by occlusal forces as experienced during biting hard objects such as hard candy, nuts etc in the oral environment. The adhesive should be capable of withstanding such forces. This mastication-induced force is reported to be around 6 to 8 MPa (ref 1). The experimental procedure for determining if the adhesive can support this shear load is outlined here.

Experimental procedure for determining shear bond strength

Bond brackets to surface abraded acrylic rod, 1" diameter and 2" long. (as discussed above). Clamp the Rod to a table overhang with a C-clamp. Using a wire harness load the bracket with static weights up to 24 pounds. This load translates to stress of 10 MPa, based on the bracket base surface area (mesio-distal width (0.138") X occluso-gingival height (0.148"). The experimental set-up is shown in figure (1). Repeat the experiment with 5 different brackets for both the candidate adhesives. All brackets should pass the 24 lb static load to meet clinical survival standards. (Ref. 1).

References:

(1) Reynolds I.R., A review of direct orthodontic bonding. Br. J Orthod. 1975:2:171-178.

Results of comparison studies including, set-time, and shear bond strength.

Test Criterion	*510(k) Device (Lion Se)*	*Predicate Device (Reli-On)*
Physical characteristics:		
a) Paste	white, translucent thick paste	White, translucent thick paste
b) Activator	Clear liquid, acrylic odor	Clear liquid, acrylic odor
Set-Time (seconds) (average of 5 trials)	32	29
Shear bond strength (MPa) (pass/fail based on published data, ref. 1)	> 8MPa (pass)	> 8 MPa (pass)
Ultimate Shear bond strength (MPa)	9.1 MPa	9.4 MPa

Conceptual design of the adhesive system

The adhesive system is made up of two primary components, a thick paste and a liquid activator. The activator, which contains the amine catalyst, is applied to the surfaces of the etched tooth surface as well as to the base of the bracket. The paste, which contains the peroxide catalyst, is then applied onto the bracket base and the bracket is positioned onto the tooth surface. The reaction proceeds from the outer surfaces towards the center.

The paste component is packaged in plastic syringes for easy delivery. The activator is packaged in a squeeze bottle. The etchant comes in a prefilled syringe. The labeling and the various components of the predicate device (Reli-On) and the device being submitted for 510(k) clearance (Lion Se) are shown elsewhere.

Conclusions

Based on these test observations, we believe that Lion Se adhesive is substantially equivalent to the predicate device Reli-On adhesive for the orthodontic application of bonding brackets to teeth.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2008

Ms. Judy Ribordy
Quality Assurance Manager
Classone Orthodontics, Incorporated
5064 50th Street
Lubbock, Texas 79414

Re: K080445
Trade/Device Name: Lion Se One Step Orthodontic Adhesive
~~Regulation Number: 872.3750~~
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: July 3, 2008
Received: July 7, 2008

Dear Ms Ribordy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080445

Device Name: Lion Se One Step Orthodontic Adhesive

Indications for Use: This device is intended for bonding brackets to teeth for orthodontic treatment.

Prescription Use N/A (Part 21CFR 801 Subpart D) AND/OR Over-The-Counter Use N/A (Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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